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EXAMINER

PREBILIC, PAUL B

ART UNIT PAPER NUMBER

3738

DATE MAILED: 01/12/2004

33

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/029,872

Applicant(s)

PUGH ET AL.

Examiner

Paul B. Prebilio

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,6,10,12,13,22,23,25-29,32-35,37 and 38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,6,10,12,13,22,23,25-27,29,32-35,37 and 38 is/are rejected.
- 7) ☒ Claim(s) 28 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

***Reopening of Prosecution for New Final Rejection***

Upon review of the amendment filed October 28, 2003 and the rejections of the Final Office action, the Examiner decided to reopen prosecution in order to give a new final Office action. In particular, the October 28, 2003 after final amendment was entered, but later found to have changes made which were not marked with editorial marks. In particular, claim 33 was amended to include a coating even though the December 18, 2002 amendment did not require such. This change was made without any editorial marks in the October 28 amendment. Furthermore, it was noted that the rejection relying on Ruys in view of Davies did not include an adequate motivational statement.

This Final Office action should be considered to be a replacement for the one mailed March 3, 2003. A new ground of rejection is applied against claim 33 since it was amended by the October 28, 2003 amendment.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 6, 12, 13, 22, 23, 25, 32, 34, and 38 are rejected under 35 U.S.C. 102(b)\* as being anticipated by Ruys (article entitled "Silicone-doped Hydroxyapatite"). Ruys anticipates the claim language where the sol-gel of Ruys is a uniform mixture of hydroxylapatite and silicone which is converted to alpha-TCP by

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sintering as claimed; see page 71 (the abstract), page 74, last paragraph, and page 76 (the section entitled "Silicon Addition"). The result of Ruys' process is a powder or bulk material. Furthermore, since the material of Ruys is the same as that claimed, it would inherently have the same resorbability and *in vivo* response as claimed; see page 72.

\*The Examiner posits that the effective filing date of the present claims is August 30, 1996 because the provisional application 60/003,157 and the earlier parent application 08/576,238 only disclosed silicon entities and not other types of entities as the present claims do. Therefore, the present claims have a later filing date because the term stabilization or the meaning of stabilization entities was broadened from the meaning it had in the parent application filed before August 30, 1996.

With regard to claim 2, the higher concentration of silicone results in primarily alpha-TCP (see page 71 of Ruys), and thus, the Examiner posits that the 50 mol% material of Ruys would inherently result in a primarily alpha-TCP material after sintering.

With regard to claim 12, the material of Ruys is the same as that claimed and disclosed, and thus, it inherently has the same solubility properties such that this claim language is fully met.

With regard to claim 25, the material of Ruys is the same as that claimed and disclosed, and thus, it inherently has the same structural properties of Figure 14 as claimed. It is noted that Figure 14 is of very poor quality such that details thereof are not readily discernable.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruys (article) alone.

With regard to claim 10, Ruys uses tetraethyl orthosilicate instead of tetrapropyl orthosilicate as claimed. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use tetrapropyl orthosilicate in place of tetraethyl orthosilicate because Applicant has not disclosed that tetrapropyl orthosilicate provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with tetraethyl orthophosphate because it is from the same class of compounds and is quite chemically similar thereto. Therefore, it would have been an obvious matter of design choice to modify Ruys to obtain the invention as specified in claim 10.

With regard to claim 26, Ruys fails to disclose the particle size as claimed. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use the claimed particle size because Applicant has not disclosed that the claimed particle size provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the claimed particle size because it is in the size range of a powder form and many chemical agents and drugs are provided in

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such a form. Therefore, it would have been an obvious matter of design choice to modify Ruys to obtain the invention as specified in claim 26.

Claims 27, 29, 35, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruys (article) in view of Davies (WO 94/26872). Ruys meets the claim language except for the presence of bone cells or their excreted materials. However, Davies teaches that it was known to prepare implants by culturing bone cells on the material or implant in order to test it; see the whole document, especially the abstract. Therefore, it would have been prima facie obvious to test the bone cell activity of the Ruys composition, as taught by Davies, in order to see how effective it is as a bone growth or ingrowth promoter which was the desire of Ruys; see page 79 of Ruys under the heading "Conclusions."

With regard to claims 27 and 29, the Examiner posits that the claimed matrix would inherently be formed in the Davies modified Ruys device due to the same device being exposed to the same cells for a sufficient time for such matrix to form.

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ruys (article) in view of Kijima et al (US 4,983,182). Ruys meets the claim language as set forth above but fails to disclose a coated form of the composition as claimed. However, Kijima teaches that it was known put similar tricalcium phosphate coatings on implants in order to make the surface biologically active such that bonding of the implant to the patient is improved; see the abstract and column 1, lines 5-27. Therefore, it is the Examiner's position that it would have been prima facie obvious to use the Ruys

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material as a coating for an implant in order to make the implant more bioactive as taught by Kijima.

***Allowable Subject Matter***

Claim 28 is objected to as containing allowable subject matter, but being dependent upon a rejected base claim. Therefore, if claim 28 were rewritten in independent form including all the limitations of the independent claim and any intervening claim, then it would be allowable over the prior art of record.

***Response to Arguments***

The arguments set forth in the Appeal Brief filed October 28, 2003 have been considered, but have been considered unpersuasive with respect to most the grounds of rejection.

In particular, the Applicants argue that insoluble tricalcium phosphate not soluble tricalcium phosphate is claimed; see page 7, first paragraph of the Appeal Brief filed October 28, 2003. However, the Examiner asserts that the term "insoluble" does not mean "degradation in physiological fluids" as argued; i.e. this argument is not commensurate with the scope of the present claims. Furthermore, claim 1 states that the "stabilized tricalcium phosphate is resorbable by osteoclasts (see lines 5-6 of claim 1). Not that this limitation is needed to meet the claim language, but Ruys discloses a range of silicone, which avoids forming biodegradable TCP (tricalcium phosphate); see the last paragraph on page 71. For this reason, the insoluble tricalcium phosphate called for in claim 1 is fully met by Ruys even when the term "insoluble" is interpreted to mean non-resorbable or non-biodegradable. Moreover, it appears that the Applicants

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are confusing solubility with degradability. Furthermore, it appears that the Applicants have merely discovered some new properties to an otherwise known product.

On page 8 of the Brief, Applicants again reiterate that the tricalcium phosphate formed in their invention is insoluble which means that it is not biodegradable (see lines 7-9 of page 8). However, as pointed out before, claim 1, lines 5-6 of the present case states that the Applicants' stabilized tricalcium phosphate is resorbable. For this reason, claim 1 appears to contradict itself if "insoluble" is interpreted as the Applicants have argued.

Furthermore, the Applicants are hereby required to provide evidence of this alleged difference between the Ruys material and the material of the presently claimed invention. MPEP 2112 is incorporated herein by reference as follows:

*ONCE A REFERENCE TEACHING PRODUCT APPEARING TO BE SUBSTANTIALLY IDENTICAL IS MADE THE BASIS OF A REJECTION, AND THE EXAMINER PRESENTS EVIDENCE OR REASONING TENDING TO SHOW INHERENCY, THE BURDEN SHIFTS TO THE APPLICANT TO SHOW AN UNOBVIOUS DIFFERENCE "[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency' under 35 U.S.C. 102, on prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. In re Fitzgerald, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).*

On the bottom of page 8 of the Brief, the Applicants argue that the bioactivity of Ruys is not demonstrated. However, the Examiner asserts that bioactivity is an inherent or intrinsic property of the material. For this reason, the Examiner asserts that Ruys



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device is as bioactive as the Applicants' material because it is the same as the Applicants' material.

Finally, the Applicants argue that Davies does not have the properties of the claimed invention, and therefore, there is no clear motivation to use it as a teaching of Ruys. In response, the Examiner notes that the Applicants must treat the Section 103 rejection as the teaching combination that it is. To argue that the secondary reference does not have features that it is not said to teach is not relevant or persuasive with respect to the rejection.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure

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outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.



Paul Prebilic  
Primary Examiner  
Art Unit 3738